BACKGROUND The Direct Flow Medical Trans-catheter Aortic Valve System has a non-metallic design with a pressurized support structure, which allows precise positioning, retrieval and full hemodynamic assessment of valve performance prior to permanent implantation. The DISCOVER registry is a European prospective multicenter study to evaluate the real-world performance of the DFM valve for the treatment of severe symptomatic aortic stenosis in extreme risk patients.

METHODS Patients with a logistic Euro Score ≥ 20 or other high surgical risk co-morbidities not reflected by the logistic Euro Score were enrolled at twenty-two (22) participating centers in Europe. All endpoint-related adverse events are being adjudicated by an independent clinical event committee. In this abstract, we provide a preliminary report on 30d results in 275 patients and 1-year results in the first 125 DISCOVER registry patients treated with a Direct Flow Medical valve. Data from additional patients will become available shortly and will be included in the presentation.

RESULTS Patients were 82.6±5.4 years, and 41% of patients were female. The logistic Euro Score and STS were 18.9±14.7% (N=273) and 8.1±8.3% (N=148), respectively. Other co-morbidities included coronary artery disease in 65.1%, prior CABG 16.7%, and chronic kidney disease 32.4%. In this population, 5.1% (n=14) of patients received a 23mm valve, 42.5% (n=117) a 25mm valve, 34.5% (n=95) a 27mm valve, and 13.1% (n=36) a 29mm valve. At 30 days, freedom from all-cause mortality was 98.2% (270/275) and freedom from death and major stroke was 96.4% (265/275). A new permanent pacemaker was implanted in 12.7% (35/275). The rate of major vascular complications was 3.6% (10/275), and the rate of acute kidney injury stage 2 or 3 was 3.3% (9/275). Paravalvular regurgitation at 30 days was none or trace in 81.0% (149/184) of patients, moderate in 2.7% (5/184) and severe in no patients, with 86.4% (159/184) in NYHA functional class I or II. At the time of abstract submission, 1 year data on 125 patients were available. In this population, freedom from all-cause mortality at 1 year was 87.2% (109/125) and freedom from all-cause mortality and major stroke was 82.4% (103/125). A new permanent pacemaker was implanted in 2.4% (3/125) of these patients between 30 days and 1 year. Paravalvular regurgitation was none or trace in 91.4% (64/70) of patients, moderate in 1.4% (1/70) and severe in no patients, and 84.0% (68/81) of patients were in NYHA functional class I or II at 1 year.

CONCLUSIONS The Direct Flow Medical Trans-catheter Aortic Valve System demonstrates excellent real-world outcomes in extreme surgical risk patients with severe aortic stenosis.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS Aortic stenosis, Repositionability, TAVR

TCT-108

Initial Clinical Experience Performing Robotic Percutaneous Coronary Intervention from the Radial Approach

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BACKGROUND Recently, a robotic system for performing remote-controlled angioplasty and stent placement was approved for clinical use in the US. This robotic system allows the operator to perform percutaneous coronary intervention (PCI) while seated in a lead-lined cockpit, thereby minimizing radiation exposure and eliminating the need for lead apparel. To date, available data describing robotic PCI have been obtained exclusively using femoral arterial access. This study was performed to describe the initial clinical experience and procedure outcomes of robotic PCI performed using radial arterial access.

METHODS Data were collected from consecutive robotic PCI cases performed at a single center using radial arterial access. Target coronary lesions were classified angiographically according to the ACC/AHA lesion classification system. The primary measure of interest was procedure success, defined as <30% residual stenosis after PCI in the absence of associated death or repeat revascularization prior to hospital discharge. Access site complications, including bleeding or radial artery occlusion, were assessed. Procedure duration, defined as the time from sheath insertion to removal of the guide catheter, was recorded and compared to all manual PCI cases performed at the same center using radial arterial access during the same time period.

RESULTS We studied 55 consecutive patients (age 62 ± 11; 78% male) undergoing robotic PCI using radial arterial access. The clinical presentation of these patients was myocardial infarction in 31%, unstable angina in 60%, and stable symptoms in 9%. Robotic PCI was attempted on 62 lesions overall, with varying baseline angiographic complexities (Type A 19%, Type B1 27%, Type B2 34%, Type C 19%). Robotic PCI resulted in procedure success in 57 of 62 (92%) lesions. In 4 of 5 cases in which procedure success was not achieved, lesions were classified as ACC/AHA Type C. None of the patients undergoing robotic PCI experienced death or repeat revascularization prior to hospital discharge and there were no access site complications. Robotic PCI was associated with a 13-minute increase in procedure duration compared to 552 consecutive PCI cases performed manually from the radial approach during the same time period (robotic PCI 68 ± 22 minutes vs. manual PCI 55 ± 26 minutes; p<0.001).

CONCLUSIONS The present observations represent preliminary evidence that robotic PCI using radial arterial access is feasible and associated with acceptable clinical outcomes. Additional studies are needed to further evaluate the clinical outcomes associated with robotic PCI and to determine if robotic PCI procedure duration, which we demonstrate to be longer than the traditional manual approach in this early clinical experience, will shorten as additional clinical experience is gained.

CATEGORIES OTHER: Vascular Access: Transradial

KEYWORDS Percutaneous coronary intervention, transradial, Radial access, Robotics

TCT-109

Two-Year Outcomes With the Fully Repositionable and Retrievable Lotus™ Transcatheter Aortic Replacement Valve in 120 High-Risk Surgical Patients With Severe Aortic Stenosis: Results From the REPRISE II CE-Mark Study

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BACKGROUND The repositionable and fully retrievable Lotus™ Valve (Boston Scientific, Marlborough, MA, USA) was designed to facilitate accurate positioning and minimize paravalvular regurgitation in patients with severe aortic stenosis. This analysis will present the first report of 2-year outcomes from the REPRISE II CE-Mark study.

METHODS The REPRISE II study is a prospective, single-arm trial that enrolled patients who are at high or extreme surgical risk and aged ≥70 years at 14 centers in Australia and Europe. Patients had severe, symptomatic calcific aortic stenosis and were deemed to be at high or extreme risk for surgery based on assessment by the Heart Team.

RESULTS Among 120 enrolled patients, the mean age was 84.4±5.3 years, 57% (68/120) were female, and mean STS Score was 7.1±4.6. The mean baseline aortic valve area was 0.7±0.2cm2 and the mean aortic valve pressure gradient was 46.4±15.0mmHg. All patients were successfully implanted with a Lotus Valve; full valve retrieval

was attempted and successfully accomplished in 6 of 6 patients. The primary performance endpoint of 30-day mean aortic valve pressure gradient was 11.5±5.2mmHg, as assessed by an independent core lab, and was significantly less than the performance goal of 18 mmHg (P<0.001). The primary safety endpoint of 30-day all-cause mortality was 4.2%. One-year follow-up data or death was available for 99.2% (119/120) of patients (1 patient withdrew consent at day 13). At 1 year, the rate of all-cause mortality was 10.9% (13/119), disabling stroke was 3.4% (4/119), and disabling bleeding was 5.9% (7/119). There were no repeat procedures for valve-related dysfunction, valve migration, embolization, or TAV-in-TAV. A total of 31.9% (38/119) patients had new permanent pacemaker implantation due to new or worsened conduction disturbance. By independent core lab adjudication, the 1-year mean aortic valve gradient was 12.6±5.7mmHg and mean aortic valve area was 1.7±0.5cm2. A total of 88.6% patients had no or trivial paravalvular aortic regurgitation at 1 year; no patient had moderate or severe paravalvular aortic regurgitation.

CONCLUSIONS The Lotus Valve has demonstrated negligible paravalvular regurgitation and low rates of death and stroke at 1 year. The 2-year results of the REPRISE II CE-Mark trial will provide the longest follow-up to date in the full cohort of 120 patients treated with the Lotus Valve; results will be available for the first time at TCT 2015.

CATEGORIES STRUCTURAL: Valvular Disease: Aortic

KEYWORDS TAVI, TAVR, Transfemoral

TCT-110

Up to One Year Follow Up Results of Transcatheter Annuloplasty Ring Multicentre Trial

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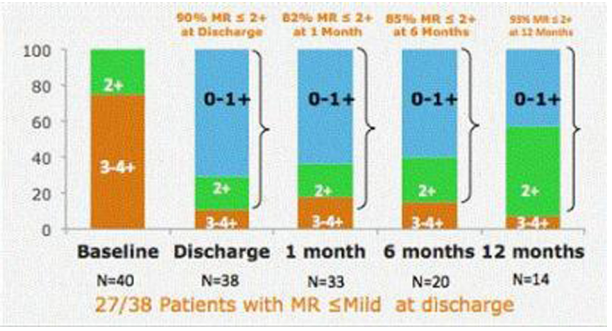
BACKGROUND The Cardioband system enables percutaneous implantation of an adjustable "surgical-like" mitral annuloplasty ring using a transseptal approach. The aim of this study was to evaluate the feasibility, safety and up to 12 month outcome of Cardioband in patients with secondary mitral regurgitation (MR) in a multicentre study.

METHODS Between February 2013 and March 2015, 40 high-risk patients with significant secondary MR were enrolled at 6 sites in Europe. After a Heart Team evaluation all patients were screened by echocardiography and cardiac CT to assess feasibility. Echocardiographic data were analyzed by an independent core-lab. Mean age was 72±7 years; thirty patients were male (75%). Mean EuroScore II 9.0%± 7.02% and median STS score 7.2 % (1.0%-34.0%). At baseline 93% of patients were in NYHA class III-IV with mean left ventricular ejection fraction of 33.3±10% (15%-57%). Device implantation was feasible in all patients (100%).

RESULTS Acute procedural success (device successfully implanted with acute reduction of MR <2+) was achieved in 92% of the patients (37/40). After cinching of the device, an average 20% reduction in the septo-lateral diameter was observed (from 37±5 mm to 29±5 mm; p<0.01). Thirty-day mortality was 5.0% (adjudicated as unrelated to the device). At 6-month follow-up (N=20) 80% of patients were in NYHA class I-II with significant improvement in quality of life (MLWHFQ from 38 to 18; p<0.05) and 85% of patients had MR≤2+. At 12 month follow-up (N=14), 70% of patients were in NYHA class I-II with significant improvement in quality of life (MLWHFQ from 35 to 17; p<0.05 and significant improvement in 6MW from 288 m to 360 m; p<0.05); 93% of patients had MR<2+).



CONCLUSIONS Transseptal direct annuloplasty with an adjustable "surgical-like" ring is feasible, with a comparable safety profile similar to other transcatheter mitral procedures. Effective reduction in MR severity is observed in most patients related to a significant septo-lateral dimension reduction. MR reduction is stable and consistent up to 12 months, with clinical benefit.

CATEGORIES STRUCTURAL: Valvular Disease: Mitral

TCT-111

Impact of Concomitant Mitral Regurgitation Following Transcatheter Aortic Valve Replacement: Insights from the US TVT National Registry

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BACKGROUND Mitral regurgitation (MR) frequently accompanies aortic stenosis (AS). Transcatheter aortic valve replacement (TAVR) is an effective treatment for severe AS, but unlike surgical treatment, cannot simultaneously address MR. The impact of concomitant MR on TAVR outcomes requires better understanding, as does the impact of TAVR on MR severity.

METHODS Patients who underwent TAVR between 1/2012 and 12/2013 in the STS-ACC TVT registry were analyzed for baseline and procedural characteristics, in-hospital and 30 day clinical outcomes as well as echo outcomes. Center for Medicare and Medicaid Services data was obtained for longer-term outcomes.

RESULTS Of 11,221 patients who underwent TAVR, 3,497 (31%) had baseline moderate (2+) MR and 602 (5%) had severe (3 to 4+) MR. As compared to patients with minimal MR (0, trace, or 1+), patients with moderate or severe MR were older, more often female, more likely NYHA class III-IV, had more atrial fibrillation/flutter, and were more likely to have a preoperative pacemaker. Patients with minimal MR had more diabetes, chronic severe lung disease, and need for home O2. Echo/cath showed patients with moderate or severe MR had lower ejection fractions, higher pulmonary artery systolic and wedge pressures. STS predicted 30-day mortality in minimal, moderate and severe MR patients were 8.1%, 9.6% and 10.7% respectively (p < 0.0001). MR improved at least 1 grade on post-procedure (pre-discharge) echocardiogram in 79% of the severe MR patients and 66% of the moderate MR patients. Unadjusted death at 30 days in the minimal, moderate and severe MR patients was 6.7%, 8.5% and 12.6%, respectively (p<0.0001). Unadjusted death at 1 year was 22.3%, 27.1% and 28.2%, respectively (p<0.0001). (Figure)

CONCLUSIONS Approximately one-third of patients presenting for TAVR in US have moderate to severe preoperative MR.